CLAIMS

[1. A test strip, having an indentation along an edge for tactile identification of a sample application port, said test strip comprising:

a first insulating substrate having first and second surfaces, an indentation along an edge and a vent hole;

at least two electrically conductive tracks affixed to the first surface of the first insulating substrate;

a second insulating substrate having first and second surfaces, an indentation along an edge, and first and second openings, the second surface being affixed to the conductive tracks and the first surface of the first insulating substrate, the first opening exposing a portion of the conductive tracks for electrical connection to a meter capable of measuring an electrical property, the second opening being located along said edge and exposing a different portion of the conductive tracks and the vent hole;

a test reagent overlaying at least a portion of the conductive tracks exposed by the second opening; and

a roof having first and second surfaces and an indentation along an edge, the second surface of the roof being affixed to the first surface of the second insulating substrate and positioned so that the second surface of the roof and the surface of the first insulating substrate form opposing walls of a capillary fill chamber with a sample application port at said edge of the second insulating substrate, wherein the second opening in the second insulating substrate and the indentations in the first insulating substrate, the second insulating substrate, and the roof are aligned to thereby provide for tactile identification of the sample application port. ]

[2. The test strip of claim 1, wherein the second surface of the roof includes a hydrophilic coating. ]

[3. The test strip of claim 1, wherein the test reagent includes

reaction components appropriate for performing a test and from about 1.75% by weight to about 17.5% by weight polyethylene oxide having a mean molecular weight from about 100 kilodaltons to about 900 kilodaltons,

wherein the reagent will redissolve or resuspend upon addition of an aqueous test sample to the reagent. ]

[4. The test strip of claim 1, wherein the test reagent includes reaction components appropriate for performing a test, and a dissolvable or suspendable film forming mixture including from about 0.2% by weight to about 2% by weight polyethylene oxide having a mean molecular weight from about 100 kilodaltons to about 900 kilodaltons,

wherein the test reagent may be applied to the test strip in a wet form, may be subsequently dried, and then redissolved or resuspended upon addition of an aqueous test sample to the dried reagent. ]

[5. The test strip of claim 4, wherein the second surface of the roof includes a hydrophilic coating. ]

[6. The test strip of claim 1, wherein the roof has a solid transparent or translucent window, which is dimensioned and positioned so that the window overlays the entire width of the electrically conductive track that is closest to the indentation of the first insulating substrate and at least about ten percent of the width of the other electrically conductive track. ]

[7. The test strip of claim 6, wherein the second surface of the roof includes a hydrophilic coating. ]

[8. The test strip of claim 6, wherein the test reagent includes

reaction components appropriate for performing a test and from about 1.75% by weight to about 17.5% by weight polyethylene oxide having a mean molecular weight from about 100 kilodaltons to about 900 kilodaltons,

wherein the reagent will redissolve or resuspend upon addition of an aqueous test sample to the reagent. ]

[9. The test strip of claim 6, wherein the test reagent includes reaction components appropriate for performing a test, and a dissolvable or suspendable film forming mixture including from about 0.2% by weight to about 2% by weight polyethylene oxide having a mean molecular weight from about 100 kilodaltons to about 900 kilodaltons,

wherein the test reagent may be applied to the test strip in a wet form, may be subsequently dried, and then redissolved or resuspended upon addition of an aqueous test sample to the dried reagent. ]

[10. The test strip of claim 9, wherein the second surface of the roof includes a hydrophilic coating. ]

[11. The test strip of claim 1, further comprising:

a first notch along the indentation in the first insulating substrate, and a notch along the indentation in the roof, both first and second notches being positioned so that they overlay one another. ]

[12. The test strip of claim 11, wherein the second surface of the roof includes a hydrophilic coating. ]

[13. The test strip of claim 11, wherein the test reagent includes

reaction components appropriate for performing a test and from about 1.75% by weight to about 17.5% by weight polyethylene oxide having a mean molecular weight from about 100 kilodaltons to about 900 kilodaltons,

wherein the reagent will redissolve or resuspend upon addition of an aqueous test sample to the reagent. ]

[14. The test strip of claim 11, wherein the test reagent includes reaction components appropriate for performing a test, and a dissolvable or suspendable film forming mixture including from about 0.2% by weight to about 2% by weight polyethylene oxide having a mean molecular weight from about 100 kilodaltons to about 900 kilodaltons,

wherein the test reagent may be applied to the test strip in a wet form, may be subsequently dried, and then redissolved or resuspended upon addition of an aqueous test sample to the dried reagent. ]

[15. The test strip of claim 14, wherein the second surface of the roof includes a hydrophilic coating. ]

[16. The test strip of claim 11 wherein the roof has a solid transparent or translucent window, which is dimensioned and positioned so that the window overlays the entire width of the electrically conductive track that is closest to the indentation of the first insulating substrate and at least about ten percent of the width of the other electrically conductive track. ]

[17. The test strip of claim 16, wherein the second surface of the roof includes a hydrophilic coating. ]

[18. The test strip of claim 16, wherein the test reagent includes reaction components appropriate for performing a test, and a dissolvable or suspendable film forming mixture

including from about 0.2% by weight to about 2% by weight polyethylene oxide having a mean molecular weight from about 100 kilodaltons to about 900 kilodaltons,

wherein the test reagent may be applied to the test strip in a wet form, may be subsequently dried, and then redissolved or resuspended upon addition of an aqueous test sample to the dried reagent. ]

[19. The test strip of claim 18, wherein the second surface of the roof includes a hydrophilic coating. ]

[20. The test strip of claim 16, wherein the test reagent includes reaction components appropriate for the test, and a dissolvable or suspendable film forming mixture including from about 0.2% weight to about 2% by weight polyethylene oxide having a mean molecular weight of 300 kilodaltons. ]

[21. The test strip of claim 20, wherein the polyethylene oxide is about 0.71% by weight. ]

[22. The test strip of claim 16, wherein the test reagent includes

reaction components appropriate for performing a test and from about 1.75% by weight to about 17.5% by weight polyethylene oxide having a mean molecular weight from about 100 kilodaltons to about 900 kilodaltons,

wherein the reagent will redissolve or resuspend upon addition of an aqueous test sample to the reagent. ]

[23. The test strip of claim 22, wherein the mean molecular weight of the polyethylene oxide is 300 kilodaltons. ]

[24. The test strip of claim 23, wherein the amount of polyethylene oxide, in the reagent is about 6.2% by weight. ]

[25. A test strip comprising:

a first insulating substrate having first and second surfaces, a notch along an edge, and a vent hole;

at least two electrically conductive tracks affixed to the first surface of the first insulating substrate;

a second insulating substrate having first and second surfaces and first and second openings, the second surface being affixed to the conductive tracks and the first surface of the first insulating substrate, the first opening exposing a portion of the conductive tracks for electrical connection to a meter capable of measuring an electrical property, the second opening being located along an edge of the second insulating substrate and exposing a different portion of the conductive tracks, the notch in the first insulating substrate, and the vent hole;

a test reagent overlaying at least a portion of the conductive tracks exposed by the second opening; and

a roof having first and second surfaces and a notch along an edge, the second surface of the roof being affixed to the first surface of the second insulating substrate and positioned so that 1) the second surface of the roof and the first surface of the first insulating substrate form opposing walls of a capillary fill chamber with a sample application port at said edge of the second insulating substrate, and 2) the notch in the roof overlays the notch in the first insulating substrate;

whereby the notch in the roof and the notch in the first insulating substrate will cause a liquid aqueous sample, when touched to the sample application port, to flow into the capillary chamber without significant hesitation. ]

[26. A test strip, comprising:

a first insulating substrate having first and second surfaces and a vent hole;

at least two electrically conductive tracks affixed to the first surface of the first insulating substrate;

a second insulating substrate having first and second surfaces and first and second openings, the second surface being affixed to the conductive tracks and the first surface of the first insulating substrate, the first opening exposing a portion of the conductive tracks for electrical connection to a meter capable of measuring an electrical property, the second opening being located along an edge of the second insulating substrate and exposing a different portion of the conductive tracks and the vent hole;

a test reagent overlaying at least a portion of the conductive tracks exposed by the second opening; and

a roof having first and second surfaces and a solid transparent or translucent window, the second surface of the roof being affixed to the first surface of the second insulating substrate and positioned so that it overlays the second opening of the second insulating substrate and so that the second surface of the roof and the first surface of the first insulating substrate form opposing walls of a capillary fill chamber with a sample application port at said edge of the second insulating substrate, and the transparent or translucent window being dimensioned and positioned so that the window extends from the sample application port, and overlays the entire width of one of the electrically conductive tracks and at least about ten percent of the width of the other electrically conductive track. ]

[27. A test strip, having an indentation along an edge for tactile identification of a sample application port, said test strip comprising:

a first insulating substrate having first and second surfaces and an indentation along an edge;

at least two electrically conductive tracks affixed to the first surface of the first insulating substrate;

a second insulating substrate having first and second surfaces, an indentation along an edge and an opening, the second surface being affixed to the conductive tracks and the first surface of the first insulating substrate, the second insulating substrate configured to expose a portion of the conductive tracks for electrical connection to a meter capable of measuring an electrical property, the opening being located along said edge and exposing a different portion of the conductive tracks;

a test reagent overlaying at least a portion of the conductive tracks exposed by the opening;

a roof having first and second surfaces and an indentation along an edge, the second surface of the roof being affixed to the first surface of the second insulating substrate and positioned so as to overlay the opening and so that the second surface of the roof and the first surface of the first insulating substrate form opposing walls of a capillary fill chamber with a sample application port at said edge of the second insulating substrate; and

a vent hole communicating with the capillary fill chamber;

wherein the opening in the second insulating substrate and the indentations in the first insulating substrate, the second insulating substrate, and the roof are aligned to thereby provide for tactile identification of the sample application port. ]

[28. The test strip of claim 27, wherein the roof has a solid transparent or translucent window, which is dimensioned and positioned so that the window overlays the entire width of

the electrically conductive track that is closest to the indentation of the first insulating substrate and at least about ten percent of the width of the other electrically conductive track. ]

[29. The test strip of claim 27 further comprising a first notch along the indentation of the first insulating substrate, and a notch along the indentation in the roof, both first and second notches being positioned so that they overlay one another. ]

[30. The test strip of claim 29 wherein the roof has a solid transparent or translucent window, which is dimensioned and positioned so that the window overlays the entire width of the electrically conductive track that is closest to the indentation of the first insulating substrate and at least about ten percent of the width of the other electrically conductive track.]

[31. A test strip comprising:

a first insulating substrate having first and second surfaces and a notch along an edge;

at least two electrically conductive tracks affixed to the first surface of the first insulating substrate;

a second insulating substrate having first and second surfaces and an opening, the second surface being affixed to the conductive tracks and the first surface of the first insulating substrate, the second insulating substrate configured to expose a portion of the conductive tracks for electrical connection to a meter capable of measuring an electrical property, the opening being located along an edge of the second insulating substrate and exposing a different portion of the conductive tracks, aid overlaying the notch in the first insulating substrate;

a test reagent overlaying at least a portion of the conductive tracks exposed by the opening;

a roof having first and second surfaces and a notch along an edge, the second surface of the roof being affixed to the first surface of the second insulating substrate and positioned so that 1) the second surface of the roof and the first surface of the first insulating substrate form opposing walls of a capillary fill chamber with a sample application port at said edge of the second insulating substrate, and 2) the notch in the roof overlays the notch in the first insulating substrate; and

a vent hole communicating with the capillary fill chamber;

whereby the notch in the roof and the notch in the first insulating substrate will cause a liquid aqueous sample, when touched to the sample application port, to flow into the capillary chamber without significant hesitation. ]

[32. A test strip comprising:

a first insulating substrate having first and second surfaces;

at least two electrically conductive tracks affixed to the first surface of the first insulating substrate;

a second insulating substrate having first and second surfaces and an opening, the second surface being affixed to the conductive tracks and the first surface of the first insulating substrate, the second insulating substrate configured to expose a portion of the conductive tracks for electrical connection to a meter capable of measuring an electrical property, the opening being located along an edge of the second insulating substrate and exposing a different portion of the conductive tracks;

a test reagent overlaying at least a portion of the conductive tracks exposed by the opening;

a roof having first and second surfaces and a solid transparent or translucent window, the second surface of the roof being affixed to the first surface of the second insulating substrate and positioned so that it overlays the opening of the second insulating substrate and so that the second surface of the roof and the first surface of the first insulating substrate form opposing walls of a capillary fill chamber with a sample application port at said edge of the second insulating substrate, and the transparent or translucent window being dimensioned and positioned so that the window extends from the sample application port, and overlays the entire width of one of the electrically conductive tracks and at least about ten percent of the width of the other electrically conductive track; and

a vent hole communicating with the capillary fill chamber.]

33-103. Cancelled.

104. (New) An electrochemical test strip for conducting testing for the concentration of glucose in a blood sample, comprising:

a strip body including an edge extending about the perimeter of said strip body, said strip body defining a capillary channel and a vent in fluid communication with the capillary channel, said strip body comprising a sample application port open at a location along the edge, the capillary channel extending from the sample application port to at least the vent;

at least working and counter electrodes spaced from each other and positioned within the capillary channel at a location spaced from the perimetric edge;

a test reagent adjacent at least the working electrode; and

visualization means associated with the capillary channel for enabling a user to visually identify when a sufficient amount of blood sample has been added to the capillary fill chamber to accurately perform a test, said visualization means including a solid,

transparent or translucent viewing material extending from at least adjacent the sample application port and overlying at least a portion of the capillary channel including at said working electrode and at least a portion of said counter electrode.

105. (New) The test strip of claim 104 in which said visualization means includes a means for identifying when a minimum sample amount has been added to the capillary channel.

106. (New) The test strip of claim 104 in which said visualization means includes said strip body including a color in the area adjacent the capillary channel which contrasts with the color of the sample as viewed through the viewing material, whereby the user is able to visually locate the sample within the capillary channel by observation through the viewing material.

107. (New) The test strip of claim 104 in which said strip body includes opposed sides of the capillary channel, the sides being parallel and extending in a straight line from the sample application port, and orthogonal to the perimetric edge, to at least one of the electrodes.

108. (New) The test strip of claim 107 in which said strip body further includes opaque portions generally aligned with the opposed sides of the capillary channel from adjacent the sample application port to at least one of the electrodes.

109. (New) The test strip of claim 108 in which the opaque portions are spaced apart to reveal greater than about 75% of the width of the capillary channel.

110. (New) The test strip of claim 109 in which the opaque portions are aligned with the opposed sides of the capillary channel.

111. (New) The test strip of claim 104 in which said strip body includes a first substrate, a second substrate and a roof, the second substrate being positioned intermediate the first substrate and the roof and including an opening, the opening of the second substrate together with the first substrate and the roof defining the capillary channel.

112. (New) The test strip of claim 111 in which said test strip includes conductive tracks connected with said working and counter electrodes, the first substrate having first and second surfaces, the working and counter electrodes being affixed to the first surface of the first substrate, the second substrate having first and second surfaces and an opening, the second surface of the second substrate being affixed to the first surface of the first substrate, the second substrate configured to expose a portion of the conductive tracks for electrical connection to a meter capable of measuring an electrical property, the opening being located along a perimetric edge of the second substrate and exposing said electrodes, and a roof having first and second surfaces and including a solid, transparent or translucent viewing material, the second surface of the roof being affixed to the first surface of the second substrate and positioned so that it overlays the opening of the second substrate and so that the second surface of the roof and the first surface of the first substrate form opposing walls of the capillary channel, the transparent or translucent viewing material extending from at least adjacent to the sample application port and overlying the entire width of one of the electrodes and at least about ten percent of the width of the other electrode.

113. (New) The test strip of claim 111 in which the second substrate defines opposed sides of the capillary channel, the sides being parallel and extending in a straight line from the sample application port, and orthogonal to the perimetric edge, to at least one of the electrodes.

114. (New) The test strip of claim 113 in which said test strip further includes opaque portions generally aligned with the opposed sides of the capillary channel from adjacent the sample application port to at least one of the electrodes.

115. (New) The test strip of claim 114 in which the opaque portions are spaced apart to reveal greater than about 75% of the width of the capillary channel.

116. (New) The test strip of claim 115 in which the opaque portions are aligned with the opposed sides of the capillary channel.

117. (New) The test strip of claim 116 in which the opaque portions are defined by the roof.

118. (New) The test strip of claim 111 in which the opening of the second substrate defines opposed sides of the capillary channel, said visualization means including opaque portions generally aligned with the opposed sides of the capillary channel extending from adjacent the sample application port to at least one of the electrodes, the opaque portions being located in the area adjacent the capillary channel, the opaque portions having a color which contrasts with the color of the sample as observed through the viewing material,

whereby a user is able to visually locate the sample within the capillary channel by observation through the viewing material and is able to determine when the sample has filled the capillary channel at least up to the at least one electrode.

119. (New) The test strip of claim 118 in which the opposed sides of the capillary channel are parallel and extend in a straight line from the sample application port, and orthogonal to the perimetric edge, to at least one of the electrodes.

120. (New) An electrochemical test strip for conducting testing for the concentration of glucose in a blood sample, comprising:

an electrochemical test strip having a capillary channel including length and width dimensions; and

a solid, transparent or translucent visualization portion including a viewing material including a viewing area through which a portion of the blood sample within the capillary channel can be visually viewed,

wherein the viewing area of the viewing material is smaller than the area defined by the length and width of the capillary channel.

121. (New) The test strip of claim 120, wherein the viewing material operates as a confirmation window that confirms sufficient blood sample has been added to the test strip to conduct a glucose test.

122. (New) The test strip of claim 120, wherein the capillary channel is bounded on at least three sides by opaque portions that provide a color contrast between the blood sample as viewed through the viewing material and the opaque portions for ease of visually determining sample sufficiency to conduct a glucose test.

123. (New) The test strip of claim 120 in which the length of the viewing area is less than the length of the capillary channel.

124. (New) The test strip of claim 120 in which the width of the viewing area is less than the width of the capillary channel.

125. (New) The test strip of claim 124 in which the length of the viewing area is less than the length of the capillary channel.

126. (New) An electrochemical test strip for conducting testing for the concentration of an analyte in a blood sample, comprising:

a strip body including an edge extending about the perimeter of said strip body, said strip body defining a capillary channel and a vent in fluid communication with the capillary channel, said strip body comprising a sample application port open at a location along the edge, the capillary channel extending from the sample application port at least to the vent;

at least working and counter electrodes spaced from each other and positioned within the capillary channel at a location spaced from the perimetric edge; and

a test reagent adjacent at least the working electrode;

said strip body defining a viewing area allowing continuous visualization of the capillary channel from a portion thereof at or generally adjacent the sample application port, up to and including said working electrode and at least a portion of said counter electrode,

the viewing area being positioned and dimensioned such that blood introduced to the capillary channel through the sample application port and filling the viewing area at least up to a portion of said counter electrode under the viewing area is required for the test strip to have a sufficient blood sample to conduct a test.

127. (New) An electrochemical test strip for conducting testing for the concentration of glucose in a blood sample, comprising:

a strip body including an edge extending about the perimeter of said strip body, said strip body defining a capillary channel and a vent in fluid communication with the capillary channel, said strip body comprising a sample application port open at a location along the perimetric edge, the capillary channel extending from the sample application port to at least the vent, said strip body further defining a test area along the capillary channel between the sample application port and the vent;

at least working and counter electrodes spaced from each other and positioned within the test area of the capillary channel at a location spaced from the perimetric edge;

a test reagent received within the test area of the capillary channel and adjacent at least the working electrode;

said strip body including a solid, transparent or translucent viewing material overlying at least a portion of the capillary channel, including from a portion thereof at or generally adjacent the sample application port continuously up to and including said working electrode and at least a portion of said counter electrode, the viewing material permitting visualization of the blood sample as it moves through the capillary channel to the test area;

said strip body further including opaque portions defining a fill area viewable through the viewing material, the fill area comprising an area of the capillary channel needed to be filled to conduct an accurate test;

wherein observation through the viewing material of the blood sample within the capillary channel up to said electrodes comprises confirmation of sufficient blood sample being introduced into the capillary channel to conduct a test.

128. (New) The test strip of claim 127 in which the opaque portions are sized and dimensioned such that the blood sample is required to fill up to the electrodes the portion of the capillary channel viewable through the viewing material in order to have a sufficient amount of blood sample to conduct a test.

129. (New) The test strip of claim 127 in which the opaque portions extend continuously in alignment with the opposed sides of the capillary channel from the perimetric edge to the electrodes.

130. (New) The test strip of claim 129 in which the opaque portions are sized and dimensioned such that the blood sample is required to fill up to the electrodes the portion of the capillary channel viewable through the viewing material in order to have a sufficient amount of blood sample to conduct a test.